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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/900,220	07/24/97	MIAO	N ONV044.01

HM12/1026

PATENT GROUP
FOLEY HOAG AND ELIOT
ONE POST OFFICE SQUARE
BOSTON MA 02109

EXAMINER	
WILSON, M	
ART UNIT	PAPER NUMBER
1633	15

DATE MAILED: 10/26/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/900,220	Applicant(s) Miao et al.
	Examiner Wilson, Michael C.	Group Art Unit 1633

☒ Responsive to communication(s) filed on *Sep 29, 1999*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-48* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-48* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 9-29-99, paper number 14, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/900220 is acceptable and a CPA has been established. An action on the CPA follows.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-27, drawn to a method of contacting cells with a ptc therapeutic, classified in class 536, subclass 23.1.

II. Claim 28, drawn to a method of limiting damage to neuronal cells comprising administering a gene activation construct, classified in class 514, subclass 2.

III. Claims 29-34, drawn to a polypeptide, classified in class 530, subclass 350.

IV. Claims 35-40 and 42-48, drawn to a nucleic acid, classified in class 536, subclass 232.1.

V. Claim 51, drawn to a method of making a polypeptide, classified in class 435, subclass 70.1.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to <u>different</u> related but distinct **methods**,

restriction is deemed to be proper because these **methods** appear to constitute patentably distinct inventions.

Groups I and II are distinct inventions because the method of contacting cells with a ptc therapeutic requires different reagents and protocols than using a gene activation construct. The gene activation construct requires the intracellular machinery to make protein which is not required for the ptc therapeutics. Therefore, the methods have different modes of operation. The method of Group I is not required for the method of Group II and vice versa.

Groups I and III are related as process of use and a product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of Groups I or II can be practiced using nucleic acids and the polypeptide of Group III can be used to isolate antibodies.

Groups I and IV are unrelated because the method of contacting cells with a therapeutic can be used for therapy while the nucleic acid can be used to make protein. The protocols and reagents required for each group are materially distinct and separate. The method of contacting cells does not require the nucleic acid sequence and the nucleic acid sequence does not require the method of contacting cells.

Groups I and V are distinct inventions because the method of contacting cells with a ptc therapeutic is used for therapy while the method of isolating a protein from a cell is used to make

protein. The protocols and reagents required for each group are materially distinct and separate. The method of contacting cells does not require the method of making protein and the method of making protein does not require the method of contacting cells.

Groups II and III are unrelated because the method of using a gene activation construct does not require the polypeptide and the polypeptide does not require the method of using a gene activation construct. The method of using a gene activation construct can be used for therapy while the polypeptide can be used to isolate antibodies.

Groups II and IV are unrelated because the method of using a gene activation construct can be used for therapy while the nucleic acid can be used to make a probe. The method of therapy does not require the probe and the probe does not require the method of therapy. The protocols and reagent required for therapy are materially distinct and separate than those required to use a nucleic acid as a probe.

Groups II and V are distinct inventions because the method of using a gene activation construct can be used for therapy while the method of isolating a protein from a cell is used to make protein. The protocols and reagents required for using a nucleic acid for therapy are materially distinct and separate from those required to isolate protein. The method of using a gene activation construct does not require the method of making protein and the method of making protein does not require the method of using a gene activation construct.

Groups III and IV are unrelated because the polypeptide can be used to isolate antibodies while the nucleic acid can be used to make protein. The protocols and reagents required for using

a nucleic acid for therapy are materially distinct and separate from those required to use a polypeptide. The polypeptide does not require the nucleic acid and the nucleic acid does not require the polypeptide.

Groups III and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method of isolating protein may be practiced by isolating the protein directly from a cell which naturally produces the protein. The polypeptide may be used in the process of isolating antibodies.

Groups IV and V are unrelated because the nucleic acid may be used to make a probe while the method of isolating a protein from a cell is used to make protein. The protocols and reagents required to use nucleic acids are materially distinct and separate than those required to isolate proteins from a cell. The nucleic acid is not required for the method of isolating proteins and the method of isolating proteins does not require the nucleic acid.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for one Group is not required for any of the other Groups, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

1) Antisense (claims 13-15),

2) a small organic molecule (claim 16),

3) Protein Kinase A inhibitor (claims 17-21),

4) Nucleic acid SEQ ID NO:7 or 8 (claims 36 and 44), or

5) Polypeptide SEQ ID NO: 16 or 17 (claims 30 and 35).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Antisense, small organic molecules, protein kinase A inhibitors, nucleic acid SEQ ID NO:7 and 8 and polypeptide SEQ ID NO: 16 and 17 differ from one another in structure, function and

mode of action. Therefore, the groups have different issues regarding patentability and enablement and represent patentably distinct subject matter.

Currently, claims 1-12 and 22-27 are generic. If applicants elect species 1, the generic claims will be considered with claims directed toward antisense only as they relate to antisense (claims 1-15 and 22-27). If applicants elect species 2, the generic claims will be considered with claims directed toward small organic molecules only as they relate to small organic molecules (claims 1-12, 16 and 22-27) wherein said small organic molecules are different than antisense, protein kinase A inhibitors, SEQ ID NO:7, 8, 16 or 17. If applicants elect species 3, the generic claims will be considered with claims directed toward protein kinase inhibitors only as they relate to protein kinase inhibitors (claims 1-12, 17-27). If applicants elect species 4, the generic claims will be considered as they relate to SEQ ID NO:7 or 8 (claims 1-12 and 22-27). If applicants elect species 5, the generic claims will be considered as they relate to SEQ ID NO:16 or 17 (claims 1-12 and 22-27).

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations

of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson whose telephone number is (703) 305-0120. The examiner can normally be reached on Monday through Friday from 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 305-0196.

Michael C. Wilson

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER